

# UWI2016-07-01 - Compliance (Dataset 1) Data Dictionary

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## Document Summary

Property	Value
Document Title	UWI2016-07-01 - Compliance (Dataset 1): Data Dictionary
Date Created	01/02/2026
Sections	3
Entries	29
Document Filename	dictionary_compliance1.rtf

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# UWI2016-07-01 - Compliance (Dataset 1): Data Dictionary

## Section 1: Identifiers

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Class	Variable	Label	Description	Format Text
01. Principal	<b>SEQUENCE_NO_</b>	Patient ID		Numeric

## Section 2: Study-wide

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Class	Variable	Label	Description	Format Text
01. Principal	<b>ARM</b>	Arm		"ACTOplus XR/Placebo"="ACTOplus XR/Placebo"
01. Principal	<b>CYCLE</b>	Cycle		Char
01. Principal	<b>DAY_1</b>	Day		Numeric
01. Principal	<b>FORM</b>	Form		"CP_DCP_Compliance V2"="CP_DCP_Compliance V2"
01. Principal	<b>FORM_DESC_</b>	Form Description		"Built for UW16110"="Built for UW16110"
01. Principal	<b>FORM_STATUS</b>	Form Status		"Amended"="Amended" "Completed"="Completed"
01. Principal	<b>LEVEL</b>	Level		Char
01. Principal	<b>MDS_DCPProtocolNumber</b>	DCP Protocol Number	Unique alphanumeric identifier assigned to a protocol by the National Cancer Institute for reporting of data.	"UWI2016-07-01"="UWI2016-07-01"
01. Principal	<b>MDS_RegisteringInstitution</b>	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022" "WI020"="WI020"
01. Principal	<b>NOT_APPLICABLE_OR_MISSING</b>	Not Applicable Or Missing		Char
01. Principal	<b>PHASE</b>	Phase		"Treatment"="Treatment"
01. Principal	<b>SEGMENT</b>	Segment		"Day 15-22 (max day 26)"="Day 15-22 (max day 26)"
01. Principal	<b>VISIT_DATE</b>	Visit Date		SAS Date

## Section 3: Compliance (Dataset 1)

Class	Variable	Label	Description	Format Text
01. Principal	<b>Amountofagentmissing</b>	Amount Of Agent Missing/Not Accounted For This Period (Tabs)	The amount that describes how much of the agent was missing or not accounted for.	Numeric
01. Principal	<b>Amountofagentprovided</b>	Amount Of Agent Provided At Last Visit (Tabs)	The amount of agent that was provided at the last visit.	Numeric
01. Principal	<b>Amountofagentreturned</b>	Amount Of Agent Returned This Visit (Tabs)	The amount that describes how much of the agent was returned by the participant.	Numeric
01. Principal	<b>Amountofagenttaken</b>	Amount Of Agent Taken During This Period (Tabs)	The amount that describes how much of the agent was actually taken.	Numeric
01. Principal	<b>DATEFirstDosetakenthisperiod</b>	First Dose Taken This Period DATE	The date the participant started taking the agent for the specified visit period.	SAS Date
01. Principal	<b>DATELastdosetakenthisperiod</b>	Last Dose Taken This Period DATE	The date the participant finished taking the agent for the specified visit period.	SAS Date
01. Principal	<b>Dateofdispenseofagent</b>	Date Of Dispense Of Agent	The date the agent was given to the participant.	SAS Date
01. Principal	<b>IfNospecifyreasonnonc</b>	If No, Specify Reason For Noncompliance	The text that describes the reason the participant was noncompliant.	Char
01. Principal	<b>IfYesindicateumberinterr</b>	If Yes, Indicate Number Of Interruptions This Period	The number that specifies the additional agent interruptions.	Numeric
01. Principal	<b>IfYesindicateumberofmod</b>	If Yes, Indicate Number Of Modifications This Period	The number that specifies the modification to the study agent	Char
01. Principal	<b>Istheparticipantcompliant</b>	Is The Participant Compliant With Protocol Intervention?	The indicator that represents whether the participant was compliant with the protocol intervention.	"Yes"="Yes"
01. Principal	<b>TIMEFirstDosetakenthisperiod</b>	First Dose Taken This Period Time	The time the participant started taking the agent for the specified visit period.	Numeric

Class	Variable	Label	Description	Format Text
01. Principal	<b>TIMELastdosetakeninthisperiod</b>	Last Dose Taken This Period Time	The time the participant finished taking the agent for the specified visit period.	Numeric
01. Principal	<b>Wasagentinterrupted</b>	Was Agent Interrupted During This Period?	The indicator representing if the agent was interrupted during the period.	"No"="No" "Yes"="Yes"
01. Principal	<b>Wasagentregimenmodified</b>	Was Agent Regimen Modified During This Period?	The indicator representing if the agent was modified.	"No"="No"